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March 31, 2023

The Honorable Gregory B. Williams
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.; C.A. No. 21-1015 (GBW)

Dear Judge Williams:

Pursuant to paragraph 5 of the Scheduling Order (D.I. 143), Counter-Plaintiff/Defendant Sarepta Therapeutics, Inc. (“Sarepta”) respectfully submits this reply to the opposition (D.I. 179) of Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) to Sarepta’s motion to amend its answer to join the patent owner, The University of Western Australia (“UWA”), as a counter-plaintiff on Sarepta’s infringement counterclaims (D.I. 175, 176).

NS does not dispute that joinder of UWA as a counter-plaintiff is legally appropriate. Indeed, NS concedes that it **“does not take issue with the legal merits of joinder”** provided that UWA joins the case as a party who is subject to typical party discovery obligations.” (D.I. 179, 1 (emphasis added).) In opposing joinder, however, NS misconstrues Sarepta’s motion as proposing joinder of UWA as a “limited” party. *See, e.g., id.* (“But Sarepta proposes that UWA be joined as a ‘limited’ party that need not comply with typical discovery obligations.”). Sarepta has proposed no such thing: Sarepta has moved to join UWA **as a counter-plaintiff**, not a party without discovery obligations. (D.I. 175, 176.) NS’s opposition is thus based on an inaccurate characterization of Sarepta’s motion.

NS similarly overstates the purported discovery disputes between the parties. According to NS, “UWA’s counsel has made plain that UWA will not undertake” to comply with a series of discovery demands listed in NS’s opposition and that “UWA’s refusal to timely undertake” its discovery obligations will prejudice NS. (D.I. 179, 2, 3.) But UWA has *not* refused to participate in discovery. Nothing in the correspondence attached to NS’s opposition shows any “refusal” by UWA to cooperate in discovery. (D.I. 179, Ex. A.) NS cannot manufacture a “refusal” to cooperate through attorney rhetoric or establish prejudice to NS where none exists.

UWA is an Australian research university that has consented to voluntarily join this case solely to address any perceived standing deficiency in connection with Sarepta’s infringement

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counterclaims. Sarepta therefore noted in its motion to amend that UWA's discovery obligations should be reasonably commensurate with that limited involvement in this case – in other words, proportional to the needs of the case. (D.I. 176, 3.) Nonetheless, as summarized below, UWA intends to cooperate in discovery once joined as a party:

Protective Order - UWA will join in the protective order after becoming a party.

Initial Disclosures - UWA will provide initial disclosures after becoming a party.

Infringement and Validity Contentions - UWA will adopt Sarepta's initial contentions relating to the infringement and validity of the UWA Patents.

Claim Construction - UWA will join in Sarepta's claim construction briefing and rely on Sarepta's oral arguments at the upcoming claim construction hearing (scheduled for May 3). UWA will not request any additional oral argument time.

Discovery Responses – UWA will join in Sarepta's previously served objections and responses to NS's discovery requests. UWA will respond to any new discovery requests served by NS within 30 days. Sarepta has already produced the laboratory notebooks relating to the experimental work leading to the UWA Patents. There is ample time in the schedule for NS to serve additional discovery requests before fact discovery closes on July 27, 2023. NS does not argue otherwise.

Core Technical Documents - NS's request for UWA to serve core technical documents is inappropriate. UWA is not (and will not be) a defendant to any infringement claim. The District of Delaware Default Standard relating to *an accused infringer's* production of core technical documents does not apply to UWA, which will only be a counter-plaintiff. See Delaware Default Standard, ¶ 4(b) ("Within 30 days after receipt of the above, each defendant shall produce to the plaintiff the core technical documents related to the *accused product(s)*....") The Court should reject this unsupported request.

Because UWA will cooperate in discovery, joinder of UWA will not prejudice NS. To the extent any future dispute arises between NS and UWA over the proper scope of discovery from UWA, the Scheduling Order already provides a specific procedural mechanism for resolving discovery disputes. (D.I. 143, ¶ 4(g).)

Sarepta therefore respectfully requests that the Court grant its motion and allow Sarepta to file its First Amended Answer joining UWA as a counter-plaintiff.

Respectfully,

/s/ *Megan E. Dellinger*

Megan E. Dellinger (#5739)

MED/rah

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)